



AA

03 CD

ATTORNEY'S DOCKET NO: C1039/7057 (HCL/MAT)  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis, et al.  
Serial No.: 09/965,101  
For: VECTORS AND METHODS FOR IMMUNIZATION OR THERAPEUTIC  
PROTOCOLS  
Filed: September 26, 2001  
Examiner: Not yet assigned  
Art Unit: Not yet assigned

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on November 12, 2001.

Maria A. Trevisan Reg. No.: 48,207

Commissioner for Patents  
Washington, D.C. 20231

**TRANSMITTAL**

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement/1449/references cited
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No fee is required. If any fee is determined to be due by the Examiner, the Examiner is authorized to charged the appropriate fee to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully Submitted,

Maria A. Trevisan, Reg. No. 48,207  
Wolf, Greenfield & Sacks, P.C.  
Federal Reserve Plaza, 600 Atlantic Avenue  
Boston, MA 02210-2211  
(617)720-3500  
Attorneys for Applicants

Attorney Docket No. C1039/7057  
Date: November 12, 2001  
xndd



ATTORNEY'S DOCKET NO: C1039/7057 (HCL/MAT)  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis, et al.  
Serial No.: 09/965,101  
For: VECTORS AND METHODS FOR IMMUNIZATION OR THERAPEUTIC  
PROTOCOLS  
Filed: September 26, 2001  
Examiner: Not yet assigned  
Art Unit: Not yet assigned

---

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on the 12 day of September, 2001.

Maria A. Trevisan Reg. No.: 48,207

---

Commissioner for Patents  
Washington, D.C. 20231

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed within three months of the filing date of a National Application.

No fee or certification is required.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application (copies enclosed):

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Title of Application</u>
C1037/7013	09/776,479	02/02/01	Immunostimulatory Nucleic Acids for the Treatment of Asthma and Allergy
C1037/7016	09/009,634	01/21/98	Immune Stimulation by Phosphorothioate Oligonucleotide Analogs
C1037/7017	09/800,266	03/05/01	Immunostimulatory Nucleic Acids and Cancer Medicament Combination Therapy for Treatment of Cancer
C1037/7018	09/801,893	03/08/01	Nucleic Acids for the Treatment of Disorders Associated with Microorganisms
C1037/7019	09/920,313	08/01/01	Nucleic Acids for Prevention and Treatment of Gastric Ulcers
C1037/7021	09/949,194	09/07/01	Nucleic Acids for the Prevention and Treatment of Sexually Transmitted Diseases
C1039/7017	09/191, 170	11/13/98	Immunostimulatory Nucleic Acid Molecules for Activating Dendritic Cells
C1039/7020	09/337,584	06/21/99	Methods for Treating Allergic and Asthmatic Disorders Using Immunostimulatory Oligonucleotides
C1039/7021	09/337,619	06/21/99	Methods for Treating Cancer Using Immunostimulatory Oligonucleotides
C1039/7022	09/337,893	06/21/99	Methods of Redirecting an Immune Response Using Immunostimulatory Oligonucleotides
C1039/7023	09/337,636	06/21/99	Immunostimulatory Nucleic Acid Molecules

<b>C1039/7025</b>	<b>09/325,193</b>	<b>06/03/99</b>	<b>Use of Nucleic Acids Containing Unmethylated CpG Oligonucleotides as an Adjuvant</b>
<b>C1039/7027</b>	<b>09/306,281</b>	<b>05/06/99</b>	<b>Methods for the Prevention and Treatment of Parasitic Infections and Related Diseases Using CpG Oligonucleotide</b>
<b>C1039/7028</b>	<b>09/361,575</b>	<b>07/27/99</b>	<b>Stereoisomers of CpG Oligonucleotides and Related Methods</b>
<b>C1039/7029</b>	<b>09/415,142</b>	<b>10/09/99</b>	<b>Immunomodulatory Oligonucleotides</b>
<b>C1039/7035</b>	<b>09/669,187</b>	<b>09/25/00</b>	<b>Immunostimulatory Nucleic Acids</b>
<b>C1039/7036</b>	<b>09/559,140</b>	<b>04/27/00</b>	<b>Screening Assays for Identifying Inhibitors, Mimics, Agonists, Antagonists and Binding Compounds</b>
<b>C1039/7041</b>	<b>09/655,319</b>	<b>09/05/00</b>	<b>Immunostimulatory Oligonucleotides</b>
<b>C1039/7042</b>	<b>09/630,319</b>	<b>07/31/00</b>	<b>Methods for Treating and Preventing of Infectious Disease</b>
<b>C1039/7043</b>	<b>09/629,477</b>	<b>07/31/00</b>	<b>Methods for Treating and Preventing of Disease in Non-Human Animals</b>
<b>C1039/7044</b>	<b>09/672,126</b>	<b>09/27/00</b>	<b>Methods Related to Immunostimulatory Nucleic Acid-Induced Interferon</b>
<b>C1039/7048</b>	<b>09/818,918</b>	<b>03/27/01</b>	<b>Immunostimulatory Nucleic Acid Molecules</b>
<b>C1039/7049</b>	<b>09/824,468</b>	<b>04/02/01</b>	<b>Methods and Products for Stimulating the Immune System Using Immunotherapeutic Oligonucleotides and Cytokines</b>

<b>C1039/7052</b>	<b>09/888,326</b>	<b>06/22/01</b>	<b>Methods for Enhancing Antibody Induced Cell Lysis and Treating Cancer</b>
<b>C1039/7053</b>	<b>09/931,583</b>	<b>08/16/01</b>	<b>Methods and Products for Treating HIV Infection</b>
<b>C1040/7004</b>	<b>09/146,072</b>	<b>09/02/98</b>	<b>Nucleotide Vector, Composition Containing Such Vector and Vaccine for Immunization Against Hepatitis</b>
<b>C1040/7006</b>	<b>09/316,199</b>	<b>05/21/99</b>	<b>Methods and Products for Inducing Mucosal Immunity</b>
<b>C1040/7010</b>	<b>09/768,012</b>	<b>01/22/01</b>	<b>Immunostimulatory Nucleic Acids for Inducing a Th2 Immune Response</b>
<b>C1041/7002</b>	<b>09/241,653</b>	<b>02/02/99</b>	<b>Methods for Regulating Hematopoiesis Using Immunostimulatory CpG- Oligonucleotides</b>
<b>C1041/7005</b>	<b>09/355,254</b>	<b>02/22/00</b>	<b>Pharmaceutical Compositions Comprising a Polynucleotide and Optionally an Antigen Especially for Vaccination</b>
<b>C1041/7010</b>	<b>09/786,436</b>	<b>03/20/01</b>	<b>G-motif Oligonucleotides and Uses Thereof</b>
<b>C1041/7014</b>	<b>09/895, 007</b>	<b>06/28/01</b>	<b>Immunostimulatory Nucleic Acids for the Treatment for Anemia, Thrombocytopenia and Neutropenia</b>

**PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited**

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

The following are remarks concerning the other information cited:

PART IV: Remarks

Documents cited on the attached form PTO-1449 (modified) are enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By: 

Maria A. Trevisan, Reg No. 48,207  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, MA 02210  
Telephone (617) 720-3500

Docket No. C1039/7057 (HCL/MAT)  
Dated: November 12, 2001  
xndd



<b>FORM PTO-1449 (Modified)</b>  <b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>	<b>APP. DOCKET NO.:</b> C1039/7057		<b>SERIAL NO.:</b> 09/965,101
	<b>APPLICANT:</b> Davis, et al.		
	<b>FILING DATE:</b> September 26, 2001	<b>GROUP:</b> Not Yet Assigned	

### U.S. PATENT DOCUMENTS

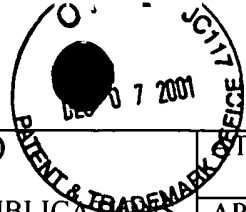
Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
	*A1	3,906,092	09/16/75	Hilleman et al.	424	089	
	*A2	4,844,904	07/04/89	Hamaguchi et al.	424	450	
	*A3	4,863,740	09/05/89	Kissel et al.	424	450	
	*A4	4,975,282	12/04/90	Cullis et al.	424	450	
	*A5	5,000,959	03/19/91	Iga et al.	424	450	
	*A6	5,248,670	09/28/93	Draper et al.	514	44	
	*A7	5,580,859	12/03/96	Felgner et al.	514	44	
	*A8	5,585,479	12/17/96	Hoke et al.	536	24.5	
	*A9	5,589,466	12/31/96	Felgner et al.	514	44	
	*A10	5,663,153	09/02/97	Hutcherson et al.	514	44	
	*A11	5,679,647	10/21/97	Carson et al.	514	44	
	*A12	5,723,335	03/03/98	Hutcherson et al.	435	375	
	*A13	5,780,448	07/14/98	Davis et al.	514	44	
	*A14	5,786,189	07/28/98	Locht et al.	435	172.3	
	*A15	5,849,719	12/15/98	Carson et al.	514	44	10/04/96
	A16	6,194,388 B1	02/27/01	Krieg, et al.			
	A17	6,207,646 B1	03/27/01	Krieg, et al.			
	A18	6,239,116 B1	05/29/01	Krieg, et al.			
	A19	6,214,806 B1	04/10/01	Krieg, et al.			
	A20	6,218,371 B1	04/17/01	Krieg, et al.			

### FOREIGN PATENT DOCUMENTS

	Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No	
	*B1	WO 90/11092	10/04/90	PCT - Vical (Felgner)	A61K	48/00	
	*B2	WO 91/12811	09/05/91	PCT - Isis Pharmaceuticals (Draper)	A61K	31/70	
	*B3	0468520 A3	01/29/92	EPO - Mitsui Toatsu Chem. (Tokunaga)	A61K	31/70	
	*B4	WO 92/03456	03/05/92	PCT - Isis Pharmaceuticals (Anderson)	C07H	15/12	
	*B5	WO 92/18522	10/29/92	PCT - Salk Institute (Chu)	C07H	21/00	
	*B6	WO 92/21353	12/10/92	PCT - Genta (Arnold)	A61K	31/70	
	*B7	0302758 B1	03/16/94	EPO - NEMC (Androphy)	C12N	15/37	
	*B8	WO 94/19945	09/15/94	PCT - Isis Pharmaceuticals (Draper)	A01N	43/04	
	*B9	WO 95/05853	03/02/95	PCT - Regents of U. of Cal. (Carson)	A61K	48/00	
	*B10	WO 95/26204	10/05/95	PCT - Isis Pharmaceuticals (Hutcherson)	A61K	48/00	
	*B11	WO 96/02555	02/01/96	PCT - UIRF (Krieg)	C07H	21/00	
	*B12	WO 96/13277	05/09/96	PCT - Regents of U. of Cal. (Carson)	A61K	48/00	
	*B13	WO 96/14074	05/17/96	PCT - Regents of U. of Cal. (Carson)	A61K	31/70	
	*B14	WO 96/35782	11/14/96	PCT - Applied Research Systems (	C12N	15/00	
	*B15	WO 97/28259	08/07/97	PCT - Regents of U. of Cal. (Carson)	C12N	15/00	

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.



FORM PTO-1449 (Modified)  LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	CITY. DOCKET NO.: CI039/7057		SERIAL NO.: 09/965,101
	APPLICANT: DEvis, et al.		
	FILING DATE: September 26, 2001		GROUP: Not Yet Assigned

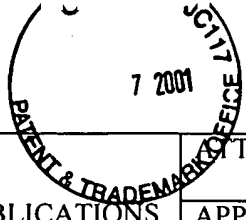
*B16	WO 98/14210	04/09/98	PCT - Regents of U. of Cal. (Carson)	A61K	39/35		
*B17	WO 98/52581	11/26/98	WIPO	A61K	35/00		
*B18	WO 99/41368A2	08/19/99	WIPO	C12N	15/10		
*B19	WO 99/41368A3	08/19/99	WIPO	C12N	15/10		
*B20	EP 0773295	05/14/97					
*B21	WO 98/18810	05/07/98	WIPO				
*B22	WO 98/37919	09/03/98	WIPO				
*B23	WO 98/40100	09/17/98	WIPO				
*B24	WO 98/52581	11/26/98	WIPO				
*B25	WO 99/51259	10/14/99	WIPO				
*B26	WO 99/56755	11/11/99	WIPO				
*B27	WO 99/58118	11/18/99	WIPO				
*B28	WO 99/61056	12/02/99	WIPO				

#### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

*C1	Adya N et al., Expansion of CREB's DNA recognition specificity by Tax results from interaction with Ala-Ala-Arg at positions 282-284 near the conserved DNA-binding domain of CREB. <i>Proc Natl Acad Sci USA</i> 91(12):5642-6, 7 Jun 1994.
*C2	Allison AC et al., The development of an adjuvant formulation that elicits cell-mediated and humoral immune responses to virus subunit and other antigens. <i>Immunopharmacology of Infections Diseases: Vaccine Adjuvants and Modulators of Non-Specific Resistance</i> , pgs. 191-201, 1987.
*C3	Angier N., Microbe DNA seen as alien by immune system, <i>New York Times</i> , 11 April 1995
*C4	Azad RF et al., Antiviral activity of a phosphorothioate oligonucleotide complementary to RNA of the human cytomegalovirus major immediate-early region. <i>Antimicrobial Agents and Chemotherapy</i> , 37:1945-1954, September, 1993.
*C5	Azuma I, Biochemical and immunological studies on cellular components of tubercle bacilli. <i>Kekkaku</i> 69(9):45-55, 1992.
*C6	Ballas ZK et al., Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. <i>J Immunol</i> 157(5):1840-5, 1996.
*C7	Bayever, E et al., Systemic administration of a phosphorothioate oligonucleotide with a sequence complementary to p53 for acute myelogenous leukemia and myelodysplastic syndrome: initial results of a phase I trial. <i>Antisense Res Dev</i> 3:383-390, 1993.
*C8	Bennett RM et al., DNA binding to human leukocytes. Evidence for a receptor-mediated association, internalization, and degradation of DNA. <i>J Clin Invest</i> 76(6):2182-90, 1985.
*C9	Berg DJ et al., Interleukin-10 is a central regulator of the response to LPS in murine models of endotoxic shock and the Schwartzman reaction but not endotoxin tolerance. <i>J Clin Invest</i> 96(5):2339-47, 1995.
*C10	Blanchard DK et al., Interferon-gamma induction by lipopolysaccharide: dependence on interleukin 2 and macrophages. <i>J Immunol</i> 136(3):963-70, 1986.
*C11	Blaxter ML et al., Genes expressed in <i>Brugia malayi</i> infective third stage larvae. <i>Molecular and Biochemical Parasitology</i> 77:77-93, 1996.
*C12	Boggs RT et al., Characterization and modulation of immune stimulation by modified oligonucleotides. <i>Antisense Nucleic Acid Drug Dev</i> 7(5):461-71, Oct 1997.
*C13	Branda RF et al., Amplification of antibody production by phosphorothioate oligodeoxynucleotides. <i>J Lab Clin Med</i> 128(3):329-38, Sep 1996.
*C14	Branda RF et al., immune stimulation by an antisense oligomer complementary to the rev gene of HIV-1. <i>Biochemical Pharmacology</i> 45(10):2037-2043, 1993.





<b>FORM PTO-1449 (Modified)</b>  <b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>	PATENT & TRADEMARK OFFICE 7 2001		Docket No.: C1039/7057	Serial No.: 09/965,101
	Applicant: Davis, et al.			
	Filing Date: September 26, 2001		Group: Not Yet Assigned	

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

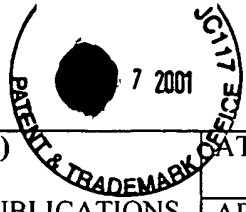
*C15	Briskin M et al., Lipopolysaccharide-unresponsive mutant pre-B-cell lines blocked in NF-kappa B activation. <i>Mol Cell Biol</i> 10(1):422-5, Jan 1990.
*C16	Burgess TL et al., The antiproliferative activity of c-myc and c-myc antisense oligonucleotides in smooth muscle cells is caused by a nonantisense mechanism. <i>Proc Natl Acad Sci USA</i> 92(9):4051-5, 1995.
*C17	Chace J et al., Regulation of differentiation in CD5+ and conventional B cells. <i>Clinical Immunology and Immunopathology</i> 68(3):327-332, 1993.
*C18	Chang YN et al., The palindromic series I repeats in the simian cytomegalovirus major immediate-early promoter behave as both strong basal enhancers and cyclic AMP response elements. <i>J Virol</i> 64(1):264-77, Jan 1990.
*C19	Chu RS et al., CpG oligodeoxynucleotides act as adjuvants that switch on T helper 1 (Th1) immunity. <i>J Exp Med</i> 186(10):1623-31, 17 Nov 1997.
*C20	Condon C et al., DNA-based immunization by in vivo transfection of dendritic cells. <i>Nat Med</i> 2(10):1122-8, 1996.
*C21	Corr M et al., Gene vaccination with naked plasmid DNA: mechanism of CTL priming. <i>J Exp Med</i> 184(4):1555-60, 1996.
*C22	Cowdery JS et al., Bacterial DNA induces NK cells to produce IFN-gamma in vivo and increases the toxicity of lipopolysaccharides. <i>J Immunol</i> 156(12):4570-5, 15 Jun 1996.
*C23	Crosby SD et al., The early response gene NGFI-C encodes a zinc finger transcriptional activator and is a member of the GCGGGGCG (GSG) element-binding protein family. <i>Mol Cell Biol</i> 2:3835-3841, 1991.
*C24	Crystal RG, Transfer of genes to humans: early lessons and obstacles to success. <i>Science</i> 270:404-410, 1995.
*C25	D'Andrea A et al., Interleukin 10 (IL-10) inhibits human lymphocyte interferon gamma-production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells. <i>J Exp Med</i> 178(3):1041-8, 1993.
*C26	Davis HL et al., CpG DNA is a potent enhancer of specific immunity in mice immunized with recombinant hepatitis B surface antigen. <i>J Immunol</i> 160(2):870-6, 1998.
*C27	Davis HL et al., Direct gene transfer into skeletal muscle in vivo: factors affecting efficiency of transfer and stability of expression. <i>Hum Gene Ther</i> 4(2):151-9, 1993.
*C28	Davis HL et al., DNA vaccine for hepatitis B: evidence for immunogenicity in chimpanzees and comparison with other vaccines. <i>Proc Natl Acad Sci USA</i> 93(14):7213-8, 1996.
*C29	Davis HL et al., DNA-based immunization induces continuous secretion of hepatitis B surface antigen and high levels of circulating antibody. <i>Hum Mol Genet</i> 2(11):1847-51, 1993.
*C30	Davis HL, Plasmid DNA expression systems for the purpose of immunization. <i>Curr Opin Biotechnol</i> 8(5):635-46, 1997.
*C31	Doe B et al., Induction of cytotoxic T lymphocytes by intramuscular immunization with plasmid DNA is facilitated by bone marrow-derived cells. <i>Proc Natl Acad Sci USA</i> 93:8578-8583, 1996.
*C32	Englich U et al., Chemically modified oligonucleotides as probes and inhibitors, <i>Angew Chem Int Ed Engl</i> 30:613-629, 1991.
*C33	Erb KJ et al., Infection of mice with Mycobacterium bovis-Bacillus Calmette-Guerin (BCG) suppresses allergen-induced airway eosinophilia. <i>J Exp Med</i> 187(4):561-9, 16 Feb 1998.
*C34	Etchart N et al., Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin. <i>J Gen Virol</i> 78(7):1577-80, 1997.
*C35	Etlinger HM, Carrier sequence selection - one key to successful vaccines. <i>Immunology Today</i> 13(2):52-55, 1992.
*C36	Fox RI, Mechanism of action of hydroxychloroquine as an antirheumatic drug. <i>Chemical Abstracts</i> , 120:15, Abstract No. 182630 (29 April 1994).
*C37	Fynan EF et al., DNA vaccines: protective immunizations by parenteral, mucosal, and gene-gun inoculations. <i>Proc Natl Acad Sci USA</i> 90(24):11478-82, 1993.
*C38	Gramzinski RA et al., Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. <i>Mol Med</i> 4(2):109-18, 1998.

FORM PTO-1449 (Modified)	ATTY. DOCKET NO.: C1039/7057	SERIAL NO.: 09/965,101
	APPLICANT: Davis, et al.	
	FILING DATE: September 26, 2001	GROUP: Not Yet Assigned

#### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

*C39	Gura, T., Antisense Has Growing Pains. <i>Science</i> 270:575-576, 1995.
*C40	Hadden JW et al., Immunopharmacology: immunomodulation and immunotherapy. <i>JAMA</i> 268(20):2964-2969, 1992.
*C41	Hadden JW, Immunostimulants. <i>TIPS</i> 14:169-174, 1993.
*C42	Halpern MD et al., Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha. <i>Cell Immunol</i> 167(1):72-8, 1996.
*C43	Harms JS and Splitter GA, Interferon-gamma inhibits transgene expression driven by SV40 or CMV promoters but augments expression driven by the mammalian MHC I promoter. <i>Hum Gene Ther</i> 6(10):1291-7, 1995.
*C44	Hatzfeld J et al., Release of early human hematopoietic progenitors from quiescence by antisense transforming growth factor $\beta$ 1 or Rb oligonucleotides. <i>J Exp Med</i> 174:925-929, 1991.
*C45	Highfield-PE, Sepsis: the more, the murkier. <i>Biotechnology</i> 12:828, 12 August 1994.
*C46	Hoeffler JP et al., Identification of multiple nuclear factors that interact with cyclic adenosine 3',5'-monophosphate response element-binding protein and activating transcription factor-2 by protein-protein interactions. <i>Mol Endocrinol</i> 5(2):256-66, Feb 1991.
*C47	Iguchi-Ariga SM and Shaffner W, CpG methylation of the cAMP-responsive enhancer/promoter sequence TGACGTCA abolishes specific factor binding as well as transcriptional activation. <i>Genes Dev</i> 3(5):612-9, May 1989.
*C48	International Search Report, PCT/US98/10408, WO 98/52581, 2 September 1998.
*C49	Ishikawa R et al., IFN induction and associated changes in splenic leukocyte distribution. <i>J Immunol</i> 150(9):3713-27, 1 May 1993.
*C50	Iversen P et al., Pharmacokinetics of an antisense phosphorothioate oligodeoxynucleotide against rev from human immunodeficiency virus type 1 in the adult male rat following single injections and continuous infusion. <i>Antisense Res Dev</i> 4:43-52, 1994.
*C51	Jakway JP et al., Growth regulation of the B lymphoma cell line WEHI-231 by anti-immunoglobulin, lipopolysaccharide, and other bacterial products. <i>J Immunol</i> 137(7):2225-31, 1 Oct 1986.
*C52	Jaroszewski JW and Cohen JS, Cellular uptake of antisense oligonucleotides. <i>Adv Drug Delivery Rev</i> 6(3):235-50, 1991.
*C53	Kimura Y et al., Binding of oligoguanylate to scavenger receptors is required for oligonucleotides to augment NK cell activity and induce IFN. <i>J Biochem</i> 116(5):991-994, 1994.
*C54	Kline JN et al., CpG motif oligonucleotides are effective in prevention of eosinophilic inflammation in a murine model of asthma. <i>J Invest Med</i> 44(7):380A, 1996.
*C55	Kline JN et al., CpG oligonucleotides can reverse as well as prevent Th2-mediated inflammation in a murine model of asthma. <i>J Invest Med</i> 45(7):298A, 1997.
*C56	Kline JN et al., Immune redirection by CpG oligonucleotides. Conversion of a Th2 response to a Th1 response in a murine model of asthma. <i>J Invest Med</i> 45(3):282A, 1997.
*C57	Klinman DM et al., Contribution of CpG motifs to the immunogenicity of DNA vaccines. <i>J Immunol</i> 158:3635, 1997.
*C58	Klinman DM et al., CpG motifs present in bacteria DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon gamma. <i>Proc Natl Acad Sci USA</i> 93(7):2879-83, 1996.
*C59	Krieg AM et al., A role for endogenous retroviral sequences in the regulation of lymphocyte activation. <i>J Immunol</i> 143:2448-2451, 1989.
*C60	Krieg AM et al., CpG DNA: A pathogenic factor in systemic lupus erythematosus? <i>J Clin Immunol</i> 15(6):284-292, 1995.
*C61	Krieg AM et al., CpG motifs in bacterial DNA trigger direct B-cell activation. <i>Nature</i> 374:546-9, 1995.
*C62	Krieg AM et al., Leukocyte stimulation by oligodeoxynucleotides. <i>Applied Antisense Oligonucleotide Technology</i> 431-448, 1998.

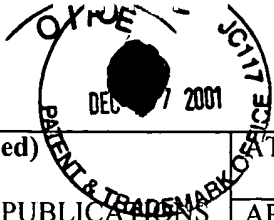


FORM PTO-1449 (Modified)  LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO.: C1039/7057	SERIAL NO.: 09/965,101
	APPLICANT: Davis, et al.	
	FILING DATE: September 26, 2001	GROUP: Not Yet Assigned

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

*C63	Krieg AM et al., Modification of antisense phosphodiester oligodeoxynucleotides by a 5' cholesteryl moiety increases cellular association and improves efficacy. <i>Proc Natl Acad Sci USA</i> 90:1048-1052, 1993.
*C64	Krieg AM et al., Oligodeoxynucleotide modifications determine the magnitude of B cell stimulation by CpG motifs. <i>Antisense Nucleic Acid Drug Dev</i> 6(2):133-9, Summer 1996.
*C65	Krieg AM et al., Phosphorothioate oligodeoxynucleotides: antisense or anti-protein? <i>Antisense Res Dev</i> 5:241, 1995.
*C66	Krieg AM et al., The role of CpG dinucleotides in DNA vaccines. <i>Trends in Microbiology</i> 6:23-27, Jan 1998.
*C67	Krieg AM et al., Uptake of oligodeoxyribonucleotides by lymphoid cells is heterogeneous and inducible. <i>Antisense Res Dev</i> 1(2):161-71, Summer 1991.
*C68	Krieg AM, An innate immune defense mechanism based on the recognition of CpG motifs in microbial DNA. <i>J Lab Clin Med</i> 128(2):128-33, 1996.
*C69	Kuramoto E et al., Oligonucleotide sequences required for natural killer cell activation. <i>Jpn J Cancer Res</i> 83:1128-1131, November 1992.
*C70	Leclerc C et al., The preferential induction of a Th1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA. <i>Cell Immunol</i> 179(2):97-106, 1997.
*C71	Leonard GA et al., Conformation of guanine 8-oxoadenine base pairs in the crystal structure of d(CGCGAATT(O8A)GCG). <i>Biochemistry</i> 31(36):8415-8420, 1992.
*C72	Lipford GB et al., CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants. <i>Eur J Immunol</i> 27(9):2340-4, 1997.
*C73	Liu MA et al., Immunization of non-human primates with DNA vaccines. <i>Vaccine</i> 15(8):909-12, 1997.
*C74	Macfarlane DE and Manzel L, Antagonism of immunostimulatory CpG-oligodeoxynucleotides by quinacrine, chloroquine, and structurally related compounds. <i>J Immunol</i> 160(3):1122-31, 1 Feb 1998.
*C75	Mannino RJ et al., Lipid matrix-based vaccines for mucosal and systemic immunization. <i>Vaccine Design: The Subunit and Adjuvant Approach</i> , Chapter 15, pp. 363-387, 1995.
*C76	Mastrangelo MJ et al., Gene therapy for human cancer. <i>Seminars in Oncology</i> 23(1):4-21, 1996.
*C77	Matson S and Krieg AM, Nonspecific suppression of [ <sup>3</sup> H]thymidine incorporation by "control" oligonucleotides. <i>Antisense Res Dev</i> 2(4):325-30, Winter 1992.
*C78	McIntyre KW et al., A sense phosphorothioate oligonucleotide directed to the initiation codon of transcription factor NF-kappa B p65 causes sequence-specific immune stimulation. <i>Antisense Res Dev</i> 3(4):309-22, Winter 1993.
*C79	Messina JP et al., Stimulation of <i>in vitro</i> murine lymphocyte proliferation by bacterial DNA. <i>J Immunol</i> 147(6):1759-1764, 15 September 1991.
*C80	Messina JP et al., The influence of DNA structure on the <i>in vitro</i> stimulation of murine lymphocytes by natural and synthetic polynucleotide antigens. <i>Cell Immunol</i> 147:148-157, 1993.
*C81	Mojcik CF et al., Administration of a phosphorothioate oligonucleotide antisense murine endogenous retroviral MCF <i>env</i> causes immune effects <i>in vivo</i> in a sequence-specific manner. <i>Clinical Immunology and Immunopathology</i> 67(2):130-136, 1993.
*C82	Mottram JC et al., A novel CDC2-related protein kinase from <i>Leishmania mexicana</i> , LmmCRK1, is post-translationally regulated during the life cycle. <i>J Biol Chem</i> 268(28):21044-21052, October 1993.
*C83	<i>New England BIOLABS 1988-1989 Catalog</i>
*C84	Nyce JW and Metzger WJ, DNA antisense therapy for asthma in an animal model. <i>Nature</i> 385:721-725, 20 Feb 1997.
*C85	Pisetsky DS and Reich C, Stimulation of <i>in vitro</i> proliferation of murine lymphocytes by synthetic oligodeoxynucleotides. <i>Mol Biol Rep</i> 18(3):217-221, 1993.
*C86	Pisetsky DS and Reich CF, Stimulation of murine lymphocyte proliferation by a phosphorothioate oligonucleotide with antisense activity for herpes simplex virus. <i>Life Science</i> 54:101-107, 1994.
*C87	Pisetsky DS, Immunologic consequences of nucleic acid therapy. <i>Antisense Res Dev</i> 5:219-225, 1995.

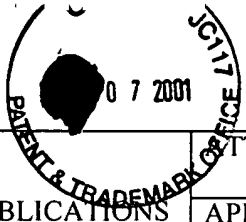


<b>FORM PTO-1449 (Modified)</b>  <b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO.: C1039/7057		SERIAL NO.: 09/965,101
	APPLICANT: Davis, et al.		
	FILING DATE: September 26, 2001		GROUP: Not Yet Assigned

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

*C88	Pisetsky DS, The immunologic properties of DNA. <i>J Immunol</i> 156(2):421-423, 1996.
*C89	Prince AM et al., Successful nucleic acid based immunization of newborn chimpanzees against hepatitis B virus. <i>Vaccine</i> 15(8):916-9, 1997.
*C90	Raz E et al., Intradermal gene immunization: the possible role of DNA uptake in the induction of cellular immunity to viruses. <i>Proc Natl Acad Sci USA</i> 91(20):9519-23, 1994.
*C91	Raz E et al., Preferential induction of a Th1 immune response and inhibition of specific IgE antibody formation by plasmid DNA immunization. <i>Proc Natl Acad Sci USA</i> 93(10):5141-5, 14 May 1996.
*C92	Roman M et al., Immunostimulatory DNA sequences function as T helper-I-promoting adjuvants. <i>Nat Med</i> 3(8):849-54, Aug 1997.
*C93	Sato Y et al., Immunostimulatory DNA sequences necessary for effective intradermal gene immunization. <i>Science</i> 273(5273):352, 19 July 1996.
*C94	Schnell N et al., Identification and characterization of a <i>Saccharomyces cerevisiae</i> gene (PAR1) conferring resistance to iron chelators. <i>Eur J Biochem</i> 200:487-493, 1991.
*C95	Schwartz DA et al., CpG motifs in bacterial DNA cause inflammation in the lower respiratory tract. <i>J Clin Invest</i> 100(1):68-73, 1 Jul 1997.
*C96	Schwartz DA et al., Endotoxin responsiveness and grain dust-induced inflammation in the lower respiratory tract. <i>Am J Physiol</i> 267(5 Pt 1):L609-17, 1994.
*C97	Schwartz DA et al., The role of endotoxin in grain dust-induced lung disease. <i>Am J Respir Crit Care Med</i> 152(2):603-8, 1995.
*C98	Shirakawa T et al., The inverse association between tuberculin responses and atopic disorder. <i>Science</i> 275(5296):77-9, 3 Jan 1997.
*C99	Sparwasser T et al., Macrophages sense pathogens via DNA motifs: induction of tumor necrosis factor- $\alpha$ -mediated shock. <i>Eur J Immunol</i> 27(7):1671-9, Jul 1997.
*C100	Stein CA et al., Oligonucleotides as inhibitors of gene expression: a review. <i>Cancer Res</i> 48:2659-2668, 1988.
*C101	Stull RA et al., Antigene, ribozyme, and aptamer nucleic acid drugs: progress and prospects. <i>Pharmaceutical Res</i> 12(4):465-483, 1995.
*C102	Subramanian PS et al., Theoretical considerations on the "spine of hydration" in the minor groove of d(CGCGAATTCGCG)-d(GCGCTTAAGCGC): Monte Carlo computer simulation. <i>Proc Natl Acad Sci USA</i> 85:1836-1840, 1988.
*C103	Tanaka T et al., An antisense oligonucleotide complementary to a sequence in Iy2b increases $\gamma$ 2b germline transcripts, stimulates B cell DNA synthesis, and inhibits immunoglobulin secretion. <i>J Exp Med</i> 175:597-607, 1992.
*C104	Tang D-C et al., Genetic immunization is a simple method for eliciting an immune response. <i>Nature</i> 356(6365):152-4, 1992.
*C105	Thorne PS, Experimental grain dust atmospheres generated by wet and dry aerosolization techniques. <i>Am J Ind Med</i> 25(1):109-12, 1994.
*C106	Tokunaga T et al., A synthetic single-stranded DNA, poly (dG,dC), induces interferon $\alpha/\beta$ and $\gamma$ , augments natural killer activity, and suppresses tumor growth. <i>Jpn J Cancer Res</i> 79:682-686, June 1988.
*C107	Tokunaga T et al., Synthetic oligonucleotides with particular base sequences form the cDNA encoding proteins of <i>Mycobacterium bovis</i> BCG induce interferons and activate natural killer cells. <i>Microbiol Immunol</i> 36(1):55-66, 1992.
*C108	Tomasi M et al., Strong mucosal adjuvanticity of cholera toxin within lipid particles of a new multiple emulsion delivery system for oral immunization. <i>Eur J Immunol</i> 27:2720-2725, 1997.
*C109	Uhlmann E et al., Antisense oligonucleotides: a new therapeutic principle. <i>Chem Rev</i> 90:543-584, 1990.
*C110	Wagner RW, Gene inhibition using antisense oligodeoxynucleotides. <i>Nature</i> 372:333-335, 1994.



FORM PTO-1449 (Modified)  LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	PRIORITY DOCKET NO.: C1039/7057		SERIAL NO.: 09/965,101
	APPLICANT: Davis, et al.		
	FILING DATE: September 26, 2001	GROUP: Not Yet Assigned	

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

*C111	Wallace RB et al., Oligonucleotide probes for the screening of recombinant DNA libraries. <i>Methods in Enzymology</i> 152:432-442, 1987.
*C112	Weiner GJ et al., Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization. <i>Proc Natl Acad Sci USA</i> 94(20):10833-7, 1997.
*C113	Weiss R, Upping the antisense ante: Scientists bet on profits from reverse genetics. <i>Science</i> 139:108-109, 1991.
*C114	Whalen RG, DNA vaccines for emerging infection diseases: what if? <i>Emerging Infectious Disease</i> 2(3):168-175, 1996.
*C115	Wu GY et al., Receptor-mediated gene delivery and expression in vivo. <i>J Biol Chem</i> 263:14621-14624, 1988.
*C116	Wu-Pong S, Oligonucleotides: opportunities for drug therapy and research. <i>Pharmaceutical Technology</i> 18:102-114, 1994.
*C117	Xiang ZQ et al., The effect of interferon-gamma on genetic immunization. <i>Vaccine</i> 15(8):896-8, 1997.
*C118	Yamamoto S et al., DNA from bacteria, but not from vertebrates, induces interferons, activates natural killer cells and inhibits tumor growth. <i>Microbiol Immunol</i> 36(9):983-97, 1992.
*C119	Yamamoto S et al., <i>In vitro</i> augmentation of natural killer cell activity and production of interferon-alpha/beta and -gamma with deoxyribonucleic acid fraction from <i>Mycobacterium bovis</i> BCG. <i>Jpn J Cancer Res</i> 79:866-73, Jul 1988.
*C120	Yamamoto S et al., Unique palindromic sequences in synthetic oligonucleotides are required to induce INF and augment INF-mediated natural killer activity. <i>J Immunol</i> 148(12):4072-4076, 15 June 1992.
*C121	Yamamoto S, Mode of action of oligonucleotide fraction extracted from <i>Mycobacterium bovis</i> BCG. <i>Kekkaku</i> 69(9):29-32, 1994.
*C122	Yamamoto T et al., Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length. <i>Antisense Res Dev</i> 4:119-123, 1994.
*C123	Yamamoto T et al., Lipofection of synthetic oligodeoxyribonucleotide having a palindromic sequence AACGTT to murine splenocytes enhances interferon production and natural killer activity. <i>Microbiol Immunol</i> 38(10):831-836, 1994.
*C124	Yamamoto T et al., Synthetic oligonucleotides with certain palindromes stimulate interferon production of human peripheral blood lymphocytes <i>in vitro</i> . <i>Jpn J Cancer Res</i> 85:775-779, 1994.
*C125	Yaswen P et al., Effects of sequence of thioated oligonucleotides on cultured human mammary epithelial cells. <i>Antisense Res Dev</i> 3(1):67-77, 1993.
*C126	Yi, A-K et al., IFN- $\gamma$ promotes IL-6 and IgM secretion in response to CpG motifs in bacterial DNA and oligonucleotides. <i>J Immunol</i> 156(2):558-564, 1996.
*C127	Yi, A-K et al., Rapid immune activation by CpG motifs in bacterial DNA. <i>J Immunol</i> 157(12):5394-5402, 1996.
*C128	Zhao Q et al., Comparison of cellular binding and uptake of antisense phosphodiester, phosphorothioate, and mixed phosphorothioate and methylphosphonate oligonucleotides. <i>Antisense Res Dev</i> 3(1):53-66, Spring 1993.
*C129	Zhao Q et al., Stage-specific oligonucleotide uptake in murine bone marrow B-cell precursors. <i>Blood</i> 84(11):3660-6, 1 Dec 1994.
*C130	Cox CJM, et al. Bovine herpes virus 1: immune responses in mice and cattle injected with plasmid DNA. <i>J. Virol</i> 1993 Sep; 67(9):5664-5667
*C131	Lipford GB et al. Immunostimulatory DNA: sequence-dependent production of potentially harmful or useful cytokines. <i>Eur J Immunol</i> 1997 Dec; 27(12):3420-3426
*C132	Morahan PS et al. Comparative analysis of modulators of nonspecific resistance against microbial infections. <i>Immunopharmacology of Infectious Diseases: Vaccine Adjuvants and Modulators of Nonspecific Resistance</i> . 1987. Alan R. Liss, pp. 313-324.
*C133	Parker SE et al. Plasmid DNA gene therapy: studies with the human interleukin-2 gene in tumor cells in vitro and in the murine B16 melanoma model in vivo. <i>Cancer Gene Therapy</i> 1996 May-Jun;3(3):175-1785

<b>FORM PTO-1449 (Modified)</b>  <b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>	<b>ACTIVITY DOCKET NO.:</b> C1039/7057	<b>SERIAL NO.:</b> 09/965,101
	<b>APPLICANT:</b> Davis, et al.	
	<b>FILING DATE:</b> September 26, 2001	<b>GROUP:</b> Not Yet Assigned

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

*C134	Ulmer JB et al. Heterologous protection against influenza by injection of DNA encoding a viral protein. Science 1993 March 19;259:1745-1749
*C135	Vogels MTE et al. Use of immune modulators in nonspecific therapy of bacterial infections. Antimicrob Agent Chemother 1992 Jan;36(1):1-5
*C136	Wang B et al. Gene inoculation generates immune responses against human immunodeficiency virus type I. Proc Natl Acad Sci USA 1993 May;90:4156-4160
*C137	Wloch MK et al. The influence of DNA sequence on the immunostimulatory properties of plasmid DNA vectors. Human Gene Therapy 1998 Jul 1;9:1439-1447
*C138	Karlin S et al. Why is CpG suppressed in the genomes of virtually all small eukaryotic viruses but not in those of large eukaryotic viruses? J Virol. 1994 May;68(5):2889-2897
*C139	Krieg AM et al. Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci USA 1998 Oct 13;95(21):12631-12636
*C140	Schreiber E et al. Long-range activation of transcription by SV40 enhancer is affected by "inhibitory" or "permissive" DNA sequences between enhancer and promoter. Somat Cell Mol Genet. 1989 Nov;15(6):591-603
*C141	Verma, et al. Gene therapy promises, problems and prospects, Nature 1997 Sept;389: 239-242
*C142	Anderson, et al. Human Gene Therapy, Nature 1998 April; 392: 25-30
*C143	McCluskie, et al. Route and Method of Delivery of DNA Vaccine Influence Immune Responses in Mice and Non-Human Primates, Molecular Medicine, 1999;5: 287-300
*C144	Cryz, et al. Vaccine Delivery Systems, Reports of the Expert Panels, Vaccine 1996;14(7): 665-688

\* A copy was cited in the parent application having serial number 09/082,649, filed May 20, 1998.

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.